UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,735	07/21/2005	Nadine Mothes	LNK-002	5394

31496 7590 01/10/2008
SMITH PATENT CONSULTING CONSULTING, LLC
3309 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,735	MOTHES ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 13-18* is/are pending in the application.

4a) Of the above claim(s) *1-6,8 and 14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 and 13-18 are pending.

2. Applicant's election with traverse of Group III, claims 7 and 13 in the reply filed on 10/17/2007 is acknowledged. The traversal is on the ground(s) that " the search required for the elected invention of Group III (i.e., the mosaic allergen of SEQ ID NO: 1) overlaps with, and indeed is central to, the search required for the non-elected invention of Group II (i.e., a DNA encoding for the mosaic allergen of SEQ ID NO: 1). Therefore, it would not be an undue burden for the Examiner to consider claims 7, 8, 13, and 14 together in the present application. Applicant argues that elected claims 7 and 13 all require a mosaic allergen having (or encoding) the amino acid sequence of SEQ ID NO: 1, Applicants respectfully submit that further election is not required.

This is not found persuasive because DNA and polypeptide searches do not overlap. Prior art which reads on the polypeptide will not necessarily read on the nucleic acid. To search two separate inventions within an application is a burden on the examiner, contrary to Applicant's assertion. The species requirement to elect a single polypeptide for Group III was proper at the time because claim 13 read on more than one polypeptide species. As amended, the claim 7 and 13 only read on a mosiac allergen comprising SEQ ID NO:1, as elected.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-6, 8 and 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/17/2007.

4. Claims 7 and 13 are currently under consideration as they read on a mosaic allergen comprising SEQ ID NO:1 and a vaccine thereof.

5. Applicant's IDS document filed on 07/20/2005 is acknowledged.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7 and 13 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a mosaic allergen consisting of SEQ ID NO:1; does not provide reasonable enablement for : A mosaic allergen **having** the amino acid sequence of SEQ ID NO:1; and a **vaccine** for the treatment of allergic patients characterized in that it comprises the mosaic allergen of claim 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

On pages 8-13 the specification discloses a medicament comprising a polypeptide consisting of SEQ ID NO:1. SEQ ID NO:1 was shown to have reduced allergenic activity in that SEQ ID NO:1 exhibited reduced IgE reactivity in a dot blot; decreased histamine release was shown by radioimmunoassay in cell-free supernatants; and skin prick tests using SEQ ID NO:1 elicited only mild reactions in grass pollen allergic patients. IgG from Rabbits that were immunized with SEQ ID NO: 1 reacted with rPhl p 2 and mosaic allergen on dot blot and inhibited the binding of IgE from serum of grass-allergic patients using ELISA by 20.93%, as compared to 54.73% inhibition of IgE binding by IgG antibodies from rabbits immunized with rPhl p 2.

The specification does not provide sufficient support for the mosaic allergen "having" the sequence of SEQ ID NO:1. The term "having" is open ended and broadens the claims to

encompass many more peptides than the specification provides enablement for with unlimited amino acids added to the N- and/or C-terminals of the peptide. As recited, the undisclosed amino acids may function to treat allergies independent of the sequence of SEQ ID NO:1. The specification does not adequately disclose the genus of mosaic allergens encompassed by the instant claim recitation for use in the claimed invention.

Also at issue is whether or not the claimed composition would function as a medicament and/or vaccine. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the vaccine as claimed, absence of working examples providing evidence which is reasonably predictive that the claimed vaccine is effective for in vivo use to treat allergy, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed vaccine with a reasonable expectation of success.

A vaccine is a composition to induce specific immunity that **prevents** or protects against a specific disease caused by a specific agent. The first criterion in judging a vaccine is the level of antibody (humoral immune response) before and after immunization. The success of the vaccination is judged by the extent of increase in the level of antigen - specific antibody. The second criterion for a vaccine is its ability to stimulate memory T lymphocytes (cell-mediated immune response) (PTO-892 Reference U; In particular, Chapter 18). The specification provides no information on the vaccine formulation comprising a mosiac allergen having the amino acids sequence of SEQ ID NO:1 which is able to exhibit antigen-specific antibody

response, stimulate memory T lymphocytes and protect or prevent against allergy. Vaccines by definition trigger an immunoprotective response in the host vaccinated and a mere antigenic response is insufficient. The specification fails to provide guidance as to how to totally prevent (100% prevention) allergy using a vaccine or medicament comprising a mosaic allergen having the amino acid sequence of SEQ ID NO:1. The invention may reduce the likelihood of an allergy by administering a mosaic allergen having the amino acid sequence of SEQ ID NO:1, but the specification does not disclose how to totally prevent allergy. Therefore, the specification does not provide sufficient guidance on how to sufficiently prevent the occurrence of allergy by administering the claimed compound.

Substantiating evidence may be in the form of animal tests, which constitute recognized screening procedures with clear relevance to efficacy in humans. See Ex parte Krepelka, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein. Ex parte Maas, 9 USPQ2d 1746.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 7 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: a mosaic allergen consisting of SEQ ID NO:1.

Applicant is not in possession of : a mosaic allergen **having** the amino acid sequence of SEQ ID NO:1.

Applicant has only disclosed SEQ ID NO:1 ; therefore, the skilled artisan cannot envision all the contemplated mosaic allergen possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties,

by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A

message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 6, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER